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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/597,394

07/24/2006

James L. Miller

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08/18/2009

PHILIPS INTELLECTUAL PROPERTY & STANDARDS

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EXAMINER

STICE, PAULA J

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

08/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,394	MILLER, JAMES L.	
	Examiner	Art Unit	
	PAULA J. STICE	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-9 and 11-24 is/are pending in the application.
- 4a) Of the above claim(s) 12-20, 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☒ Claim(s) 7-9, 11, 21 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02/29/2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/24/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment

1. This office action is responsive to the (preliminary) amendment filed on 08/10/2009. As directed by the amendment: claims 1, 7 and 21 have been amended. Thus, claims 1-5, 7-9, 11 and 21-22 are presently pending in the application.

Election/Restrictions

2. Applicant's election without traverse of 1-10 and 21-22 in the reply filed on 07/22/2009 is acknowledged.

3. Claims 11-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

4. Claims 6 and 10 have been canceled.

Claim Objections

5. Claims 1, 7, and 21 are objected to.

6. Claims 1, 7, and 21 recite the limitation "the heart in an open heart procedure" in line 2 of each of the claims. There is insufficient antecedent basis for this limitation in the claim.

7. It is suggested that the preamble of claims 1 and 7, which are device claims, be changed to "A single-handle internal defibrillator adapted to apply defibrillation electrodes directly to a heart in an open heart procedure, comprising:" This modification in the claim language would also alleviate any potential 35 USC § 101 rejections.

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8. The remainder of the claims are also objected to in that they are dependent claims of a previously objected to independent claim.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Regarding independent claim 1, in the examiners interview on 08/05/2009, Examiner Layno suggested to Mr. Yorks that the claim language of the independent claims within the application be modified to recite either 1) circuitry included in the handle of the internal defibrillator and/or 2) the switch mechanism included in the handle of the internal defibrillator. The following claim 1 rejection is based on the modification(s) suggested *not* added to this independent claim.

11. Claim 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller (US Patent Publication 2003/0191501 A1) in view of Wang et al. (US Patent Publication 2002/0058934 A1).

12. Regarding claim 1: Miller discloses a pair of paddles 200/204 (figure 2) that includes a pair of electrodes 202/206 (figure 2) respectively connected to first distal-end portions of the pair of paddles (paragraph 0026); and defibrillator circuitry coupled to the electrodes of the pair of paddles (figure 7 and "A wire 700 carrying electric current used to shock a patient's heart is connected to a handle 702" paragraph 0046). It is noted that the Miller device is a defibrillator therefore

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the defibrillator circuitry is inherently coupled to the pair of paddles through the wire 700 in order for electricity to flow. However, Miller does not disclose the pair of paddles coupled to a single-handle for holding with one hand, with at least one paddle of the pair of paddles being adjustable in position with respect to the other paddle; an adjustment mechanism, coupled to the single handle and to at least one of the paddles for adjusting the position of the electrode of the other paddle so that a distance between the electrodes is variable. Wang, however, teaches of an adjustable cardiac ablation tool (abstract) which can grasp the surface of the heart and is capable of being grasped in one hand (paragraph 0008 and figure's 3-4). The Wang device further comprises electrodes 64/68 (figure 3) which are adjustable via an adjustment mechanism / pivot 56 (figure 3), which renders device a single handle tool. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Miller to include a pair of paddles coupled to a single handle capable of being held with one hand for adjusting the electrodes which contact cardiac tissue, as taught by Wang, for the purpose of providing a single handed device which can tightly grasp the heart thereby properly positioning the electrodes to the desired location for defibrillation and/or ablation therapy.

13. Regarding claim 2: Miller as modified by Wang discloses the claim limitation of claim 1; Miller continues to disclose a locking mechanism (paragraph 0052) that retains the position of an electrode at a desired position so as to maintain a desired distance between the electrodes (paragraph 0052). It is noted that the locking collar disclosed by Miller adjusts the length of the handle

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which therefore positions the electrode to a desired length and is in respect to the distance and length of the opposing electrode.

14. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller (US Patent Publication 2003/0191501 A1) in view of Wang et al. (US Patent Publication 2002/0058934 A1) and further in view of Cox et al (US Patent 5,540,724).

15. Regarding claim 3: Miller as modified by Wang discloses the claim limitations of claim 1 except wherein the defibrillator circuitry includes a power supply. Cox however discloses a power source 70 (figure 1) within in the circuitry of an implantable cardiac defibrillator. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Miller/Wang to include a power source, as taught by Cox for the purpose of supplying energy to the device in order to achieve cardiac defibrillation.

16. Regarding claim 4: Miller as modified by Wang discloses the claim limitations of claim 1 except wherein the defibrillator circuitry includes an energy storage unit. Cox however discloses the use of a charge capacitor 92 (figure 4) which is utilized to store charge (column 7 lines 1-10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Miller/Wang to include the use of capacitors as energy storage devices, as taught by Cox for the purpose of pre-charging the electrical components to the appropriate amount prior to shocking the heart.

17. Regarding claim 5: Miller as modified by Wang discloses the claim limitations of claim 1 except the defibrillator circuitry includes a control circuit.

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Cox however teaches of a circuit which uses switches to control the amount of electrical energy applied to the heart (abstract), which is under the command of a microprocessor (column 4 lines 65-67 through column 5 lines 1-2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Miller/Wang to include the use of a control circuit, as taught by Cox, for the purpose of monitoring the amount of energy applied to the heart.

Allowable Subject Matter

18. Claims 7-9, 11 and 21-22 would be allowable if rewritten or amended to overcome the objection(s) set forth in this Office action.

19. The following is a statement of reasons for the indication of allowable subject matter:

20. Regarding independent claims 7 and 21: the prior art fails to disclose or render obvious an internal defibrillation device which contains a discharge switch at least partially contained within a single handle that can be held in one hand.

21. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAULA J. STICE whose telephone number is (571) 270-1478. The examiner can normally be reached on Monday - Friday 8AM-5PM, Est., alternating Friday's.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/PAULA J. STICE/
Examiner, Art Unit 3766

/Carl H. Layno/
Supervisory Patent Examiner, Art
Unit 3766